

CLAIMS

1. An effervescent formulation comprising oxytocin.
- 5 2. An effervescent formulation according to Claim 1 comprising multilayer effervescent microspheres.
3. An effervescent formulation according to Claim 2 wherein the multilayer effervescent microspheres contain an acidic substance, a basic
10 substance and water-soluble isolating agent.
4. An effervescent formulation according to Claim 3 wherein dissolution in water of the multilayer effervescent microspheres leads, after almost immediate effervescence, to a solution or a homogeneous dispersion
15 of the oxytocin.
5. An effervescent formulation according to Claim 4 wherein the water-soluble isolating agent is dispersed in the entire bulk of each microsphere, the latter having a two-layer structure: a layer of acidic
20 substance in which is dispersed the water-soluble isolating agent and a layer of alkaline substance in which is dispersed the water-soluble isolating agent.
6. An effervescent formulation according to Claim 4 wherein the
25 water-soluble isolating agent is in the form of a thin film separating the acidic and alkaline substances such that each microsphere has a three-layer structure: a layer of acidic substance and a layer of alkaline substance separated by a layer of water-soluble isolating agent.

7. An effervescent formulation according to any of the preceding claims wherein the oxytocin is present in a unit dose amount of from 50 ng to 100 µg.
- 5 8. An effervescent formulation according to Claim 7 wherein the oxytocin is present in a unit dose amount of 340 ng to 11 µg.
9. An effervescent formulation according to any of the preceding claims wherein the formulation is presented in a tablet form.
- 10 10. An effervescent formulation according to Claims 1 to 8 wherein the formulation is presented in a powder form.
11. An effervescent formulation according to any one of the preceding
15 claims wherein the oxytocin is present within a microsphere.
12. An effervescent formulation according to any one of Claims 1 to 11 wherein the oxytocin is not present within a microsphere.
- 20 13. An effervescent formulation according to any of the preceding claims obtained or obtainable by the process of any one of Claims 16 to 25.
14. An effervescent formulation according to any one of the previous claims for use in medicine.
- 25 15. A pharmaceutical composition comprising an effervescent formulation according to any one of Claims 1 to 13 and a pharmaceutically acceptable carrier.

16. A process for making an effervescent formulation containing oxytocin.
17. A process according to Claim 16 wherein the effervescent
5 formulation comprises multilayer effervescent microspheres containing an acidic substance, a basic substance, and a water-soluble isolating agent which upon dissolution in water leads, after almost immediate effervescence, to a solution or a homogeneous dispersion of oxytocin.
- 10 18. A process according to Claim 17 wherein the acidic and/or basic substances contains or contain oxytocin.
19. A process according to Claim 16 or Claim 17 wherein the oxytocin is not present in microspheres.
- 15 20. A process according to Claim 18 which employs the method of rotary granulation in a fluidized air bed.
21. A process according to Claims 17 to 20 wherein basic substance also
20 contains an edible dilutant and/or flavourings and/or sweeteners.
22. A process according to Claims 17 to 21 wherein the oxytocin is present in an amount to give from 50 ng to 100 µg in the final unit dosage form.
- 25 23. A process according to Claim 22 wherein the oxytocin is present in an amount to give from 340 ng to 11 µg in the final unit dosage form.
24. A process according to any one of Claims 16 to 23 further
30 comprising preparing the microspheres into a tablet.

25. A process according to Claim 24 wherein the oxytocin is present on or between the microspheres in the tablet.

5 26. An effervescent formulation of oxytocin obtained or obtainable by the process of any one of Claims 16 to 25.

27. A method of induction or augmentation of labour or treating or preventing postpartum haemorrhage or treating missed abortion or
10 facilitation of lactation comprising administering an effervescent formulation of oxytocin according to any one of Claims 1 to 13 and/or obtained or obtainable by a process as defined in any one of Claims 16 to 26 and/or a pharmaceutical composition according to Claim 15.

15 28. Use of an effervescent formulation of oxytocin according to any one of Claims 1 to 13 and/or obtained or obtainable by a process as defined in any one of Claims 16 to 26 and/or a pharmaceutical composition according to Claim 15 in the manufacture of a medicament for the induction or augmentation of labour or treatment or prevention of postpartum
20 haemorrhage or treatment of missed abortion or treatment of facilitation of lactation.